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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,986	08/12/2003	Edwin I. Stoltz	765.1056	6304
21831	7590	02/14/2006	EXAMINER	
STEINBERG & RASKIN, P.C. 1140 AVENUE OF THE AMERICAS, 15th FLOOR NEW YORK, NY 10036-5803			ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/638,986	Applicant(s) STOLTZ, EDWIN I.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 Nov 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 31-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Group I in the reply filed on November 25, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The Election of Group I without traverse has been noted. Claims 1-30 will be examined on the merits. Claims 31-36 are withdrawn from further examination.

Claims

Claim Objections

Claim 12 is objected to because of the following informalities: the claim is missing a period after the number. It is not uniform with the other claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite insofar as the basis for the percent calculation is not set forth, e.g., percent by weight based on the total weight of the composition, percent by volume based on the volume of the carrier, etc. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.) The percent calculation must either be clearly defined within the specification and set forth within the claim since w/w would, e.g., be different from w/v.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21, 23, 25-26 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoltz (US 6,251,369).

Stoltz discloses foamable fluoride dental compositions comprising fluoride, an oil in water emulsifier, a surfactant and a foam stabilizer. The water soluble fluoride component is provide in an amount to provide 0.5% to 10% by weight of available fluoride. When the water soluble fluoride component is sodium fluoride, the component is incorporated into the compositions at concentrations ranging from 1.0% to 10% by weight (col. 3, lines 20-59). The emulsifier is added to the compositions at a concentration ranging from 1.0% to 10% weight of the composition. Suitable emulsifying agents include combinations of cetyl phosphate and stearic acid such as that available from Croda, Inc. under the trade name CRODAFOS CP50. The emulsifying agents can also be added as individual components in ratios of cetyl phosphate to stearic acid ranging from about 1:4 to 4:1, which encompass claims 12-15 and 18-19. Based on the percentages of the emulsifiers in the desired compositions, the percentage of the instant claims 14 and 15 are encompassed by the ratio. This hydrophobic combination of ingredients is advantageously included in the dental foams of the invention and also contributes to maintaining the pH in the desired acidic range. For example, dental foams containing concentrations of about 2% of this hydrophobic emulsion combination result in foam pH's ranging from about 2.5 to about 3.5 which are desirable for acidulated fluoride foam products. Other emulsifying agents can be selected from the non-limiting list including oleth-3 (also known as polyoxyethylene (3) oleyl alcohol phosphate), oleth-5, oleth-10, oleth-20, steareth-10, celeth-20, mixtures thereof and the like, which encompasses claims 16, 17 and 20. Therefore oleth-3 may be combined with oleth-10, which encompasses claim 21. The compounds may also act as an

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emulsion stabilizer (col.4, lines 6-63). The surfactant comprises 0.5% to 3.0% of the composition. The surfactants include sodium N-methyl-N-cocoyl taurate, or sodium methyl cocoyl taurate, N-coco-beta-aminobutyric acid, monosodium-N-lauryl-1-glutamate, monosodium-N-cocoyl-1-glutamate and mixtures thereof (col. 5, lines 9-25). Polyethylene glycol is also used in the compositions to improve the lubricity of the composition (col. 14, lines 65-67). The compositions also contain foam stabilizers such as cetyl alcohol and sodium monostearate, as recited in claim 26. The foam stabilizers are incorporated in concentrations ranging from 0.5% to 5% by weight (col. 5, lines 29-41), which encompasses claim 25. The foam stabilizers may be considered micro-emulsion thickeners in the instant claim because they are the same compounds incorporated in substantially the same amounts. The reference anticipates the claims insofar as disclosing a foamable fluoride composition comprising fluoride, an emulsifier, a surfactant and a thickener (foam stabilizer). Alcohol is also incorporated into the compositions of the invention. Specially denatured alcohol (SDA) is also used in dental foam concentrates in accordance with the invention to maintain the fluidity of the foam concentrate in storage over a period of days. The amount of SDA in the foam composition ranges from about 2.0% to about 20.0% by weight. SDA is pure ethyl alcohol or ethanol that has been denatured with a specific denaturant permitted by the Bureau of Alcohol, Tobacco and Firearms (ATF) of the U.S. Dept. of the Treasury (col. 15, lines 24-41). This encompasses claims 28-30. Ethanol is a popular solvent, which is compatible with water soluble and water insoluble compounds. In the disclosed invention, with an oil in water emulsion, the alcohol is an ideal solvent in order to

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maintain the fluidity of the foam concentrate (col. 15, lines 53-57). The foamable compositions of the invention are packaged in an aerosol can and may be sprayed into a dental tray, which is recited in claim 1 (a) and (b) (col. 2, lines 53-67 and col. 3, lines 1-8). In regards to 1(c), the compositions disclosed by the reference comprise substantially the same compounds, i.e., a fluoride, an emulsifier, a surfactant, a micro-emulsion thickener and a clarifying agent, as the compositions disclosed and claimed by the Applicant, one would have reasonably expected that the compositions of the reference have substantially the same properties, such as transforming into a foam when engaged with the teeth, as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltz (US 6,251,369) in view of Morgan et al. (WO 01/28340).

The primary reference is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions comprising DEA oleth-3 or DEA oleth-10.

Morgan discloses antimicrobial compositions to kill bacteria and viruses on surface such as the skin and mouth. The reference discloses DEA oleth-3 phosphate and DEA oleth-10 phosphate as suitable emulsifiers for the compositions. These emulsifiers have hydrophobic lipophilic balance numbers higher than 12 (page 10, 32-37 and page 11, lines 1-9). Emulsifiers with a medium to high HLB value are good for oil-in-water emulsion compositions (the oilfield glossary by Schlumberger). The reference differs from the instant claim insofar as it does not disclose a foamable fluoride composition with a water soluble fluoride.

It would have been obvious to one of ordinary skill in the art to have used DEA oleth-3 or DEA oleth-10 in the compositions of the primary reference motivated by the desire to produce improved emulsifier qualities as disclosed by the secondary reference.

2) Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltz (US 6,251,369) in view of Smrt et al. (US 5,156,765).

The primary reference is discussed above. The reference differs from the instant claims insofar as it does not disclose using surfactants such as sodium lauryl ether sulfate.

Smrt et al. discloses an aerosol composition adapted for providing a foam upon discharge from a suitable containment means. These compositions comprise surfactants and foam stabilizing agents. The surfactant used in the present invention has a dual role. More specifically, this component will act as a dispersant for a foam stabilizer as well as a foam-inducing agent (col. 5, lines 55-58). Typical surfactants, which may be used in the aerosol compositions of the present application, are lauryl sulfate, lauryl ether sulfate, and mixtures thereof. Exemplar of a surfactant which may be added to the composition is Sipon NA-61 (sodium laureth(3) sulfate), a sodium lauryl ether sulfate as recited in the instant claim. The amount of surfactant present generally ranges from about 0.1 to about 15 wt. percent (col. 6, lines 11-19). The reference differs from the instant claims insofar as they do not disclose the foamable toothpaste compositions comprising an emulsifier.

It would have been obvious to one of ordinary skill in the art to have added the surfactants such as sodium lauryl ether sulfate in the compositions of the primary reference motivated by the desire to incorporate a surfactant for its ability to act as a foaming agent and a dispersant for a foam stabilizing components in a foamable compositions as disclosed by the secondary reference.

3) Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltz (US 6,251,369) in view of Babinski et al. (US 6,024,951).

The primary reference is disclosed above. PEG components are useful for its ability to provide lubricity to the compound. A problem with fluoride gels is especially critical when the dental tray with the gel is turned upside down to submerge the lower teeth in the fluoride-containing gel. In these situations, the gel quickly leaves the dental tray and reduces the effectiveness of the fluoride treatment is reduced (col. 1, lines 33-38). The reference differs from the instant claim insofar as it does not disclose using PEG-150 pentaerythrityl tetrastearate.

Reich et al. discloses compositions comprising PEG-150 Pentaerythriyl tetrastearate. The PEG-150 is used to improve surface adhesion of the disclosed compositions (col. 2, lines 14-18 and col. 3, lines 42-51).

It would have been obvious to one of ordinary skill in the art to use the PEG-150 as the lubricant of the primary reference because of its ability to the surface adhesion of the fluoride gel as disclosed by the secondary reference.

Obvious-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 7-27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-18 and 24 of U.S. Patent No. 5,824,289. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are coexistent because they both claim foamable fluoride compositions comprising a water-soluble fluoride, an emulsifier, a foam stabilizer or thickener (in the instant claims), and a surfactant.

2) Claims 7-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-12, 14-15 and 18-25 of U.S. Patent No. 6,251,369. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive and read on a foamable fluoride comprising a water-soluble fluoride, an emulsifier, a foam stabilizer or thickener (in the instant claims), and a surfactant.

Claims 1-30 are rejected.

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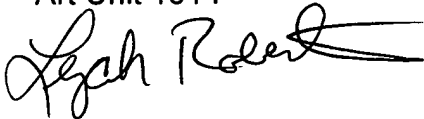
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
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